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10/006,014	12/04/2001	Chen Xing Su	10209.276	6898

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/006,014

Applicant(s)

SU ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .                      6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's request for continued examination, amendment, and response, all received on 07 July 2003.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 9, and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to Claims 2, 9, and 12 contain limitations drawn to a pre-determined dose of *Morinda citrifolia* that is between two and three ounces. It is unclear where support for this limitation comes from the originally filed disclosure.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1-10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moniz in view of Nair *et al.*, and Wadsworth *et al.*

The Moniz patent discloses background information on *Morinda citrifolia*, among which is that in the Caribbean, leaves of this plant are steamed and applied topically for aches, pains, and tendonitis (See Column 2, Lines 1-2). Other uses of the plant include extracting juice from the ripe fruit, diluting with water, and consuming the resulting mixture as a drink (See Column 1, Lines 56-66). The patent also describes a method of processing the pulp of the noni fruit into a dry powder (See Column 3, Line 41 to Column 4, Line 34). Additionally, the patent suggests problems with palatability with the juice of *Morinda citrifolia* (See Column 3, Line 36). It is the position of the examiner that even if the Moniz patent does not explicitly disclose the treatment of pain by the action of selective COX-2 inhibition, such a property is merely an inherent characteristic of the *Morinda citrifolia*. The claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

The Moniz patent does not explicitly teach a method of treating pain and inflammation comprising the use of *Morinda citrifolia* in capsule form, at a predetermined concentration, as an ingredient in a food product, or the use of the pasteurized juice or pulp of *Morinda citrifolia* in a food product.

The Nair *et al.* document discloses food supplements containing fruit extracts, which treat pain and inflammation by way of selective cyclooxygenase-2 inhibition (See Abstract; and Page 8, Lines 1-9). The document also discloses methods of identifying anti-inflammatory compounds in fruit extracts, as well as testing for COX-2 selectivity (See Pages 17-24). The

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fruit extracts may be present in powdered, liquid, or solid forms (See Page 26, Lines 1-8).

Specific forms include foods such as shakes, soups, drink, and snack bars, as well as more conventional dosage forms, which include tablets and gel caps (See Page 26, Lines 9-18). The fruit extracts may also be present in foodstuffs, to be further processed into other food products (See Page 26, Lines 19-33). Information is disclosed regarding the formulation of various embodiments of the supplements (See Page 9, Lines 6-26). Assays to test for anti-inflammatory activity are also disclosed (See Section D, Pages 21-24).

The Wadsworth *et al.* patent teaches a dietary fiber product made from *Morinda citrifolia* (See Abstract). The patent describes a method of obtaining this fiber product from the *Morinda citrifolia* fruit by filtering the wet pulp from the juice, where the pulp has a fiber content of 10% to 40% by weight. The pulp is then pasteurized, and can be further processed into a dietary product (See Column 1, Lines 43-62). Other products taught by the patent include a juice product comprising the *Morinda citrifolia* juice and puree, which are also pasteurized (See Column 2, Lines 41- 53), as well as the filtered *Morinda citrifolia* juice, which may also be pasteurized and further processed for use in nutritional products or dietary supplements (See Column 4, Lines 19-31).

It would be obvious to one of ordinary skill in the art to combine the teachings of Moniz, Nair *et al.*, and Wadsworth *et al.* into the objects of the instant application. Moniz teaches the therapeutic properties of *Morinda citrifolia*, including the treatment of pain. Although such properties were explicitly attributed only to the leaves of the plant, one of ordinary skill in the art would be motivated to use the fruit of the plant with a reasonable expectation of success, as it would be obvious that the active ingredient present in the leaves responsible for pain relief would

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likely be present in other parts of the plant as well. One of ordinary skill would be motivated to combine the teachings of Nair *et al.* with those of Moniz in order to find methods to further investigate the mechanism of pain relief that the extract of *Morinda citrifolia* provides, specifically that of selective COX-2 inhibition, as the benefits of such a mechanism of pain relief is known in the art. One of ordinary skill can have a reasonable expectation of success, given the applicability of the analysis methods disclosed by Nair *et al.* to the extracts of other fruits. Finally, one of ordinary skill would be motivated to combine the teachings of Wadworth *et al.* with Moniz, or additionally with those of Nair *et al.*, because of its direct applicability to *Morinda citrifolia*, specifically to methods of preparing the fruit for consumption in various forms in a way that is palatable to a subject while retaining its therapeutic properties. Regarding the limitation of providing *Morinda citrifolia* at a predetermined dosages and concentrations, it is the position of the examiner that it is well within the purview of one of ordinary skill in the art to determine an appropriate dosage or concentration through routine experimentation.

Thus, the claimed invention as a whole is *prima facie* obvious.

### ***Response to Arguments***

The applicant's arguments, received on 07 July 2003, have been considered, but are not found to be persuasive.

It is the position of the examiner that the additional limitations placed into the claims do not place them in condition for allowance. Limitations concerning proper dosing of a pharmaceutical preparation after consideration of a patient's characteristics are considered by the examiner to be well within the capabilities of one of ordinary skill in the art. For example, the

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Nair *et al.* reference contains disclosures regarding formulation and assays to test for pharmacological activity for both *in vitro* and *in vivo* methods. Unless the applicant can conclusively demonstrate that such limitations are not within the purview of one of ordinary skill in the art, the newly added limitations will not be considered to add an inventive element to the instantly claimed invention.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjoh  
July 25, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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